



General

Guideline Title

An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations.

Bibliographic Source(s)

Manchikanti L, Abdi S, Atluri S, Benyamin RM, Boswell MV, Buenaventura RM, Bryce DA, Burks PA, Caraway DL, Calodney AK, Cash KA, Christo PJ, Cohen SP, Colson J, Conn A, Cordner H, Coubarous S, Datta S, Deer TR, Diwan S, Falco FJ, Fellows B, Geffert S, Grider JS, Gupta S, Hameed H, Hameed M, Hansen H, Helm S 2nd, Janata JW, Justiz R, Kaye AD, Lee M, Manchikanti KN, McManus CD, Onyewu O, Parr AT, Patel VB, Racz GB, Sehgal N, Sharma ML, Simopoulos TT, Singh V, Smith HS, Snook LT, Swicegood JR, Vallejo R, Ward SP, Wargo BW, Zhu J, Hirsch JA. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. *Pain Physician*. 2013 Apr;16(2 Suppl):S49-S283. [2424 references] [PubMed](#)

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Manchikanti L, Boswell MV, Singh V, Benyamin RM, Fellows B, Abdi S, Buenaventura RM, Conn A, Datta S, Derby R, Falco FJ, Erhart S, Diwan S, Hayek SM, Helm S, Parr AT, Schultz DM, Smith HS, Wolfert LR, Hirsch JA. Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain. *Pain Physician*. 2009 Jul-Aug;12(4):699-802.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [March 22, 2016 – Opioid pain medicines](#) : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

Recommendations

Major Recommendations

These recommendations are presented in abbreviated form. Readers should refer to the text of the original guideline document for a detailed discussion of each of the following topics.

Definitions for the strength of the evidence (good, fair, poor/limited) are provided at the end of the "Major Recommendations" field.

Management of Low Back Pain

Diagnostic Selective Nerve Root Blocks

- The evidence for accuracy of diagnostic selective nerve root blocks is limited in the lumbar spine in patients with an equivocal diagnosis and involvement of multiple levels.
- Diagnostic selective nerve root blocks are recommended in the lumbar spine in select patients with an equivocal diagnosis and involvement of multiple levels.

Lumbar Discography

- The evidence for diagnostic accuracy for lumbar provocation discography is fair and the evidence for lumbar functional anesthetic discography is limited.
- Lumbar provocation discography is recommended with appropriate indications in patients with low back pain to prove a diagnostic hypothesis of discogenic pain specifically after exclusion of other sources of lumbar pain.

Diagnostic Lumbar Facet Joint Nerve Blocks

- The evidence for diagnostic lumbar facet joint nerve blocks is good with 75% to 100% pain relief as the criterion standard with controlled local anesthetic or placebo blocks.
- Diagnostic lumbar facet joint nerve blocks are recommended in patients with suspected facet joint pain.

Diagnostic Sacroiliac Joint Blocks

- The evidence for diagnostic intraarticular sacroiliac joint injections is good with 75% to 100% pain relief as the criterion standard with controlled local anesthetic or placebo blocks, and fair due to the limitation of the number of studies with 50% to 74% relief with a dual block.
- Controlled sacroiliac joint blocks with placebo or controlled comparative local anesthetic blocks are recommended when indications are satisfied with suspicion of sacroiliac joint pain.

Therapeutic Epidural Injections

- The evidence for caudal epidural, interlaminar epidural, and transforaminal epidural injections is good in managing disc herniation or radiculitis; fair for axial or discogenic pain without disc herniation, radiculitis or facet joint pain with caudal and lumbar interlaminar epidural injections, and limited with transforaminal epidural injections; fair for spinal stenosis with caudal, interlaminar, and transforaminal epidural injections; and fair for post surgery syndrome with caudal epidural injections and limited with transforaminal epidural injections.
- The recommendation for epidural injections for disc herniation is that one of the 3 approaches may be used; for spinal stenosis any of the 3 approaches are recommended; whereas for axial or discogenic pain, either lumbar interlaminar or caudal epidural injections are recommended. However for transforaminal the evidence is limited for axial or discogenic pain and post surgery syndrome.

Therapeutic Lumbar Facet Joint Interventions

- The evidence for lumbar conventional radiofrequency neurotomy is good, limited for pulsed radiofrequency neurotomy, fair to good for lumbar facet joint nerve blocks, and limited for intraarticular injections.
- Among the therapeutic facet joint interventions either conventional radiofrequency neurotomy or therapeutic facet joint nerve blocks are recommended after the appropriate diagnosis with controlled diagnostic lumbar facet joint blocks.

Therapeutic Sacroiliac Joint Interventions

- The evidence for sacroiliac cooled radiofrequency neurotomy is fair; limited for intraarticular steroid injections; limited for periarticular injections with steroids or botulinum toxin; and limited for both pulsed radiofrequency and conventional radiofrequency neurotomy.
- Due to emerging evidence for intraarticular injections, they are recommended in select cases with or without periarticular injections. Cooled radiofrequency neurotomy is recommended after appropriate diagnosis confirmed by diagnostic sacroiliac joint injections.

Percutaneous Adhesiolysis

- The evidence for lumbar epidural adhesiolysis in managing chronic low back and leg pain secondary to post lumbar surgery syndrome is fair to good and spinal stenosis is fair.
- Percutaneous adhesiolysis is recommended after failure of conservative management and fluoroscopically directed epidural injections.

Thermal Annular Procedures

- The evidence for intradiscal electrothermal therapy (IDET) and biaculoplasty is limited to fair and is limited for discTRODE.
- IDET and biaculoplasty may be performed in a select group of patients with discogenic pain nonresponsive to conservative modalities including epidural injections.

Percutaneous Disc Decompression

- The evidence for various modes of percutaneous disc decompression is limited to fair for nucleoplasty, and limited for automated percutaneous lumbar discectomy (APLD), percutaneous lumbar disc decompression, and decompressor.
- The Centers for Medicare and Medicaid Services (CMS) has issued a noncoverage decision for nucleoplasty.
- APLD and percutaneous lumbar disc decompression and nucleoplasty are recommended in select cases.

Management of Neck Pain

Cervical Provocation Discography

- The evidence for the diagnostic accuracy of cervical discography is limited.
- Cervical discography is indicated to test the diagnostic hypothesis of discogenic pain of the cervical spine in individuals who have been properly selected and screened to eliminate other sources of cervical pain.

Diagnostic Cervical Facet Joint Nerve Blocks

- The evidence for diagnostic cervical facet joint nerve blocks is good with a criterion standard of 75% or greater relief with placebo or local anesthetic controlled diagnostic blocks.
- Diagnostic cervical facet joint nerve blocks are recommended for the diagnosis of cervical facet joint pain.

Therapeutic Cervical Interlaminar Epidural Injections

- The evidence is good for cervical disc herniation or radiculitis; whereas it is fair for axial or discogenic pain, pain of spinal stenosis, and pain of post cervical surgery syndrome.
- Cervical interlaminar epidural injections are recommended for patients with chronic neck and upper extremity pain secondary to disc herniation, spinal stenosis, and post cervical surgery syndrome.

Therapeutic Cervical Facet Joint Interventions

- The evidence is fair for cervical radiofrequency neurotomy and cervical medial branch blocks, and limited for cervical intraarticular injections.
- Conventional radiofrequency neurotomy or therapeutic facet joint nerve blocks are recommended in managing chronic neck pain after the appropriate diagnosis from controlled diagnostic blocks.

Management of Thoracic Pain

Thoracic Provocation Discography

- The evidence for thoracic discography is limited.
- Thoracic discography is recommended to decide if an intervertebral disc is painful or not in rare circumstances.

Diagnostic Thoracic Facet or Zygapophyseal Joint Nerve Blocks

- The evidence for diagnostic accuracy of thoracic facet joint nerve blocks is good with a criterion standard of at least 75% pain relief with placebo or local anesthetic controlled diagnostic blocks.
- The diagnostic thoracic facet or zygapophyseal joint nerve blocks are recommended in the diagnosis of chronic thoracic pain.

Thoracic Epidural Injections

- The evidence for thoracic epidural injection in treating chronic thoracic pain is fair.
- Thoracic epidural injections are recommended for thoracic discogenic, disc-related, post surgery syndrome, or spinal stenosis pain.

Therapeutic Thoracic Facet or Zygapophyseal Joint Nerve Blocks

- The evidence is fair for therapeutic thoracic facet or zygapophyseal joint nerve blocks, limited for radiofrequency neurotomy, and none for thoracic intraarticular injections.
- Therapeutic thoracic facet or zygapophyseal joint nerve blocks are recommended.
- However, radiofrequency neurotomy and conventional radiofrequency neurotomy may be performed based on emerging evidence.

Implantables

Spinal Cord Stimulation (SCS)

- The evidence for SCS is fair in managing patients with failed back surgery syndrome (FBBS).
- SCS is indicated in chronic low back pain with lower extremity pain secondary to FBBS, after exhausting multiple conservative and interventional modalities.

Implantable Intrathecal Drug Administration Systems

- The evidence for intrathecal infusion systems is limited in managing chronic noncancer pain.
- The recommendations for intrathecal infusion pumps include recalcitrant chronic noncancer pain.

Antithrombotic and Antiplatelet Therapy

- Nonsteroidal anti-inflammatory agents (NSAIDs) including low dose aspirin do not increase the risk of spinal epidural hematoma and are not a contraindication for interventional techniques.
- However, high dose aspirin and combination of multiple drugs should be taken into consideration and may or may not be discontinued based on clinical judgment of individual risk and benefits assessment. In this regard, the simultaneous use of multiple agents that possess anticoagulant properties (e.g., NSAIDs or aspirin along with selective serotonin re-uptake inhibitors [SSRIs], fish oil, etc.) will increase the risk of morbidity and/or mortality.
- Phosphodiesterase inhibitors including dipyridamole (Persantine), Aggrenox (dipyridamole plus aspirin), and cilostazol (Pletal) do not appear to increase the risk of spinal epidural hematoma and are not a contraindication for interventional techniques (evidence – fair). They may or may not be discontinued prior to interventional techniques (evidence – good).
- Platelet aggregation inhibitors including ticlopidine (Ticlid), clopidogrel (Plavix), and prasugrel (Effient) may be continued or discontinued prior to interventional techniques (evidence – fair).
- Based on patient factors and managing cardiologist's opinion, if a decision is made to discontinue, the current recommendations are that they may be discontinued for 7 days with clopidogrel and prasugrel and/or 10 to 15 days with ticlopidine (evidence – fair).
- There is also emerging evidence that discontinuation of 3 days may be effective (evidence – limited).
- If a clinician chooses to discontinue, they may be discontinued for 7 days (evidence – limited).
- Warfarin may be continued or discontinued based on international normalized ratio (INR) achieved during therapy (evidence – good).
- For high risk interventional techniques including interlaminar epidural injections, percutaneous adhesiolysis, disc decompression, sympathetic blocks, and placement of implantables, warfarin must be discontinued for an appropriate period of time and INR of 1.4 or less must be achieved (evidence – good).
- For intermediate risk procedures such as caudal epidural injection, paravertebral interventional techniques, and peripheral joint injections, warfarin must be continued for an appropriate period of time and an INR of 2 or less may be considered (evidence – limited).
- Unfractionated heparin or low-molecular-weight heparin (LMWH) may be discontinued approximately 12 hours prior to providing interventional techniques (evidence - limited).
- Dabigatran (Pradaxa) may be stopped 2 to 4 days for major interventional techniques with high risk of bleeding in patients with creatinine clearance greater than 50 mL per minute. For low risk or paravertebral interventional techniques and caudal, it may be stopped for one day in patients with normal renal function. May be stopped at least 4 to 5 days for those with creatinine less than 50 mL per minute (evidence – limited).
- Rivaroxaban (Xarelto) may be stopped for one day or longer (evidence – limited).

Definitions:

Method for Grading the Overall Strength of the Evidence for an Intervention

Grade	Definition
Good	Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes (at least 2 consistent, higher-quality randomized controlled trials [RCTs] or studies of diagnostic test accuracy).
Fair	Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, size, or consistency of included studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes (at least one higher-quality trial or study of diagnostic test accuracy of sufficient sample size; 2 or more higher quality trials or studies of diagnostic test accuracy with some inconsistency; at least 2 consistent, lower-quality trials or studies of diagnostic test accuracy, or multiple consistent observational studies with no significant methodological flaws).
Limited or Poor	Evidence is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

Adapted from methods developed by the U.S. Preventive Services Task Force (USPSTF)

Clinical Algorithm(s)

The original guideline document contains the following algorithms:

- A comprehensive algorithm for the evaluation and management of chronic spinal pain
- An algorithmic approach to diagnosis of chronic low back pain without disc herniation
- A suggested algorithm for therapeutic interventional techniques in management of chronic low back pain
- An algorithmic approach to diagnosis of chronic neck pain without disc herniation
- A suggested algorithm for therapeutic interventional techniques in the management of chronic neck pain
- An algorithmic approach to diagnosis of chronic thoracic pain without disc herniation or radiculitis
- A suggested algorithm for therapeutic interventional techniques in the management of chronic thoracic pain

Scope

Disease/Condition(s)

Chronic spinal pain:

Neck pain
Thoracic pain
Low back pain

Guideline Category

Diagnosis

Evaluation

Management

Technology Assessment

Treatment

Clinical Specialty

Anesthesiology

Neurological Surgery

Neurology

Orthopedic Surgery

Physical Medicine and Rehabilitation

Radiology

Rheumatology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Health Plans

Managed Care Organizations

Patients

Physical Therapists

Physician Assistants

Physicians

Utilization Management

Guideline Objective(s)

- To develop evidence-based clinical practice guidelines for interventional techniques in the diagnosis and treatment of chronic spinal pain
- To provide a set of recommendations that can support existing and future guidelines by:
 - Providing strategies to manage chronic spinal pain and/or its consequences to improve the quality of clinical care
 - Providing recommendations that are generally acceptable to a wide range of specialties and agencies
 - Developing methods that are sound and transparent and highlighting the areas where further research is needed by noting deficiencies in knowledge
 - Utilizing a process which is valid, reliable, reproducible, clinically applicable, and flexible, providing clarity with a multidisciplinary process with documentation of the process in developing guidelines, along with a scheduled review
 - Systematically assessing the clinical and cost effectiveness of treatments and management strategies with an evidence-based approach through the use of systematic reviews, existing evidence-based guidelines, and individual clinical studies
 - Increasing compliance, dispelling misconceptions, contributing to appropriate patient expectations, and facilitating the improved relationship between patients, physicians, and payers

Target Population

All patients with chronic spinal pain who are eligible to undergo commonly utilized and effective interventional technique(s)

Interventions and Practices Considered

1. Management of low back pain*

- Diagnostic selective nerve root blocks
- Lumbar provocation discography
- Diagnostic lumbar facet joint nerve blocks
- Diagnostic sacroiliac joint blocks
- Therapeutic epidural injections (caudal epidural, interlaminar epidural, and transforaminal epidural injections)
- Therapeutic lumbar facet joint interventions (lumbar conventional radiofrequency neurotomy, pulsed radiofrequency neurotomy, lumbar facet joint nerve blocks, intraarticular injections)
- Therapeutic sacroiliac joint interventions (sacroiliac cooled radiofrequency neurotomy, intraarticular steroid injections, periarticular injections with steroids or botulinum toxin, pulsed radiofrequency and conventional radiofrequency neurotomy)
- Percutaneous adhesiolysis (lumbar epidural adhesiolysis)
- Thermal annular procedures (intradiscal electrothermal therapy [IDET], biaculoplasty, discTRODE)
- Percutaneous disc decompression (nucleoplasty, automated percutaneous lumbar discectomy [APLD], percutaneous lumbar disc decompression, decompressor)

2. Management of neck pain*

- Cervical provocation discography
- Diagnostic cervical facet joint nerve blocks
- Therapeutic cervical interlaminar epidural injections
- Therapeutic cervical facet joint interventions (cervical radiofrequency neurotomy, cervical medial branch blocks, cervical intraarticular injections)

3. Management of thoracic pain*

- Thoracic provocation discography
- Diagnostic thoracic facet or zygapophyseal joint nerve blocks
- Thoracic epidural injections
- Therapeutic thoracic facet or zygapophyseal joint nerve blocks, radiofrequency neurotomy, and thoracic intraarticular injections

4. Implantables*

- Spinal cord stimulation (SCS)
- Implantable intrathecal drug administration systems

5. Considerations for continuation or discontinuation of antithrombotic and antiplatelet therapy*

- Nonsteroidal anti-inflammatory agents (NSAIDs) including low dose aspirin
- Simultaneous use of multiple agents that possess anticoagulant properties (e.g., NSAIDs or aspirin along with selective serotonin re-uptake inhibitors [SSRI], fish oil, etc.)
- Phosphodiesterase inhibitors including dipyridamole (Persantine), Aggrenox (dipyridamole plus aspirin), and cilostazol (Pletal)
- Platelet aggregation inhibitors including ticlopidine (Ticlid), clopidogrel (Plavix), and prasugrel (Effient)
- Warfarin (consideration of international normalized ratio [INR])
- Unfractionated heparin or low-molecular-weight heparin (LMWH)
- Dabigatran (Pradaxa)
- Rivaroxaban (Xarelto)

*Refer to the "Major Recommendations" field of this summary. Some of the interventions carry either a poor or no recommendation because of limitations in the evidence.

Major Outcomes Considered

Diagnostic Outcome Measures

Facet Joint and Sacroiliac Joint Interventions

- Pain relief concordant with the type of controlled diagnostic blocks performed (primary outcome measure)
- Ability to perform previously painful movements without significant pain or complications (secondary outcome measure)

Discography

- Pain provocation and/or provocation pain relief concordant with the type of discography performed (primary outcome measure)

Therapeutic Outcome Measures

- Pain relief (short-term [up to 6 months] and long-term [12 months]) (primary outcome measure)
- Functional improvement; change in psychological status; return to work; reduction or elimination of opioid use, other drugs, or other interventions; and complications (secondary outcome measures)

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search

Searches were performed from the following sources without language restrictions:

1. PubMed from 1966, <http://www.ncbi.nlm.nih.gov/pubmed>
2. EMBASE from 1980, www.embase.com
3. Cochrane Library, www.thecochranelibrary.com/view/0/index.html
4. U.S. National Guideline Clearinghouse (NGC), www.guideline.gov
5. Previous systematic reviews and cross references
6. Clinical Trials, www.clinicaltrials.gov

The search period included articles from 1966 through 2012.

Search Strategy

The search strategy emphasized treating chronic spinal, non-cancer pain of various origins and spinal interventions. At least 2 of the review authors independently, in an unblinded standardized manner, performed each search. All searches were combined to obtain a unified search strategy. Any disagreements between reviewers were resolved by a third author and consensus.

Criteria for Considering Studies

Types of Studies

- Randomized controlled trials (RCTs)
- Nonrandomized observational studies
- Diagnostic accuracy studies
- Case reports and reviews for adverse effects

Types of Patients

Patients of interest were adults aged at least 18 years with chronic spinal pain of at least 3 months duration. Patients must have failed previous pharmacotherapy, exercise therapy, etc., prior to starting interventional pain management techniques.

Types of Interventions

Diagnostic and therapeutic spinal interventions appropriately performed with proper technique under image guidance (fluoroscopy, computed tomography [CT], or magnetic resonance imaging [MRI]) were included. Ultrasound-guided interventions or interventions without fluoroscopic or CT guidance were excluded.

Data Collection and Analysis

The reviews focused on randomized trials, observational studies, diagnostic accuracy studies, and reports of complications. The population of interest was patients suffering from chronic pain of spinal origin. Only epidural interventions, facet joint interventions, sacroiliac joint interventions, discography, vertebroplasty, kyphoplasty, percutaneous disc decompression, spinal cord stimulation, and implantable infusion systems were included. Reports without appropriate diagnosis, nonsystematic reviews, book chapters, and case reports were excluded.

Selection of Studies

In an unblinded, standardized manner, 2 review authors screened the abstracts of all identified studies against the inclusion criteria. All articles with possible relevance were then retrieved in full text for a comprehensive assessment of internal validity, quality, and adherence to inclusion criteria.

Inclusion and Exclusion Criteria

The following inclusion and exclusion criteria were established.

1. Are the patients described in sufficient detail to allow you to decide whether they are comparable to those that are seen in interventional pain management clinical practice?
 - A. Setting – office, hospital, outpatient, inpatient
 - B. Physician – interventional pain physician, general physician, anesthesiologist, physiatrist, neurologist, rheumatologist, orthopedic surgeon, neurosurgeon, etc.
 - C. Patient characteristics - duration of pain
 - D. Previous noninterventional techniques or surgical intervention
2. Is the intervention described well enough to enable you to provide the same for patients in interventional pain management settings?
 - A. Nature of intervention
 - B. Frequency of intervention
 - C. Duration of intervention
3. Were clinically relevant outcomes measured?
 - A. Proportion of pain relief
 - B. Disorder/specific disability
 - C. Functional improvement
 - D. Allocation of eligible and ineligible patients to return to work
 - E. Ability to work

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Method for Grading the Overall Strength of the Evidence for an Intervention

Grade	Definition
Good	Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes (at least 2 consistent, higher-quality randomized controlled trials [RCTs] or studies of diagnostic test accuracy).
Fair	Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, size, or consistency of included studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes (at least one higher-quality trial or study of diagnostic test accuracy of sufficient sample size; 2 or more higher quality trials or studies of diagnostic test accuracy with some inconsistency; at least 2 consistent, lower-quality trials or studies of diagnostic test accuracy, or multiple consistent observational studies with no significant methodological flaws).

Graded	Definition is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained
or	inconsistency between higher-quality trials, important flaws in trial design or conduct, gaps in the chain of evidence, or lack of
Poor	information on important health outcomes.

Adapted from methods developed by the U.S. Preventive Services Task Force (USPSTF)

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Evidence assessment for systematic reviews was based on methodological quality assessment criteria recommended for randomized trials, observational studies, and diagnostic studies. The methodology utilized in the systematic reviews followed the review process derived from evidence-based systematic reviews and meta-analyses of randomized trials and observational studies; Consolidated Standards of Reporting Trials (CONSORT) guidelines for the conduct of randomized trials; Strengthening the Reporting of Observational Studies in Epidemiology (STROBE); Cochrane guidelines; Standards for Reporting of Diagnostic Accuracy (STARD) studies; Quality Assessment of Diagnostic Accuracy Studies (QUADAS); Quality Appraisal of Reliability Studies (QAREL); and Chou and Huffman's guidelines.

Clinical Relevance

The clinical relevance of the included studies was evaluated according to 5 questions recommended by the Cochrane Back Review Group. Each question was scored as positive (+) if the clinical relevance item was met, negative (−) if the item was not met, and unclear (?) if data were not available to answer the question. (See Table 2 in Part I of the guidelines for a list of clinical relevance questions [see the "Availability of Companion Documents" field].)

Study Design Assessment

Randomized controlled trials (RCTs) are considered to provide the most internally valid evidence for medical decision-making. In the specialty of interventional pain management, results from clinical trials, both randomized and observational, with substantial impact on patient care, have been ruled ineffective based on flawed methodology of evidence synthesis. In one famous meta-analysis, authors proved that the evidence from randomized trials may be inaccurate. These authors attempted a meta-analysis, reviewing the available randomized trials supporting the use of parachutes to prevent injuries caused by jumping out of an airplane. There were no trials available which had been done, and they concluded that there was insufficient evidence to recommend the use of parachutes. Realizing that very few interventions in medicine work quite as definitively as parachutes, this attempted meta-analysis reminds us that some interventions are of such intuitive value that they do not require RCTs.

The World Health Organization (WHO) defines a clinical trial as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes." Very few studies in interventional pain management are RCTs and treatments even in surgery are only half as likely to be based on RCTs as treatments in internal medicine. There are multiple studies and opinions for and against randomized trials and observational studies and their importance.

Refer to Part I of the original guideline document for additional discussion of study design assessment.

Methodological Quality or Validity Assessment

The methodological quality assessment was performed by 2 review authors who independently assessed, in an unblinded standardized manner, the internal validity of all the studies. The methodological quality assessment was performed in such a manner as to avoid any discrepancies, which when identified were evaluated by a third reviewer and settled by consensus. Authors with a perceived conflict of interest for any manuscript were recused from reviewing the manuscript.

For adverse effects, confounding factors, etc., it was not possible to use quality assessment criteria. Thus, these were considered based on the interpretation of the reports published and critical analysis of the literature.

The quality of each individual article used in this analysis was assessed using Cochrane review criteria for randomized trials (see Table 4 in Part I of the original guideline document [see the "Availability of Companion Documents" field]), the Newcastle-Ottawa Scale for observational studies (see Tables 5 and 6 in Part I in the original guideline document), and the QAREL checklist for diagnostic accuracy studies (see Table 7 in Part I in the original guideline document). For nonrandomized observational studies, the patient population was required to have at least 50 total or at least 25 in each group if there were comparison groups. Even though none of these instruments or criteria has been systematically assessed, the advantages and disadvantages of each system were debated.

Each study was evaluated by at least 2 authors for stated criteria and any disagreements discussed with a third reviewer.

The QAREL checklist has been validated and also utilized in multiple systematic reviews. Each study in the final sample of eligible manuscripts was assessed using a 12-item appraisal checklist designed to assess the quality and applicability of studies. The face validity of these checklists was established by consultation with methodology experts and comparison with quality appraisal checklists used in other systematic reviews examining diagnostic reliability. This checklist was also developed in accordance with the STARD and the QUADAS appraisal tool. Studies were not given an overall numeric quality score; instead, each item was considered separately and graded as "yes," "no," "unclear," or "not applicable."

All studies were required to meet a minimum of 50% of applicable criteria. Studies scoring less were also described and provided with an opinion and a critical analysis.

Measurement of Treatment Effect in Data Synthesis (Meta-Analysis)

Data were summarized using meta-analysis when at least 5 studies per type of disorder were available meeting the inclusion criteria.

Outcome Measures

Conclusions of both qualitative and quantitative outcome measures were evaluated. Qualitative (the direction of a treatment effect) and quantitative (the magnitude of a treatment effect) conclusions were evaluated. Random-effects meta-analysis to pool data was also used.

The minimum amount of change in pain score to be clinically meaningful has been described as a 2-point change on a scale of 0 to 10 (or 20 percentage points), based on findings in trials studying general chronic pain, chronic musculoskeletal pain, and chronic low back pain. However, recent studies evaluating interventional techniques have used >50% pain relief as the cutoff threshold for clinically meaningful improvement in pain relief or functional status. Consequently, for analysis in these systematic reviews, the guideline developers utilized clinically meaningful pain relief of at least a 3-point change on an 11-point scale of 0 to 10, or 50% pain relief from the baseline, and/or a functional status improvement of 40% or more as clinically significant.

Outcomes may be assessed between the groups or in the same group from baseline to post treatment, however, some methodologists tend to focus only on between the groups. This essentially provides lack of improvement or lack of difference between the groups in an active control trial, non-inferiority, or equivalence trial. Thus, it is essential that outcomes be monitored pretreatment and posttreatment rather than between the groups or utilizing both methodologies. Consequently, in all the systematic reviews and the evidence assessment for interventional pain management, the outcomes have been assessed based on the design between the groups and in the same group pre and post treatment.

Outcome of the Studies

Randomized trials were judged to be positive if the intervention was clinically relevant and effective, either with a placebo control or an active control. This indicates that the difference in effect for the primary outcome measure is statistically significant on the conventional 5% level. In a negative study, no significant difference between the treatment groups or no improvement from baseline is identified.

Observational studies were judged to be positive if the intervention was effective, with outcomes reported at one month, 3 months, 6 months, and one year. The outcomes were judged as improvement in at least 40% of patients at distinct reference points with positive or negative results reported at one month, 3 months, 6 months, and one year.

Outcomes included the prevalence of pain and false-positive rate. Based on the above parameters, the reliability of the data derived from each study was assessed.

The advantages and disadvantages of various methodologies available are too extensive to be described in this manuscript. These have been described in various other manuscripts in the past.

Analysis of Evidence

Evidence analysis was performed based on United States Preventive Task Force (USPSTF) criteria (see the "Rating Scheme for the Strength of

the Evidence" field), which has been utilized by multiple authors. The analysis was conducted using 3 levels of evidence ranging from good, fair, and limited or poor.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Guideline Development Group Composition

The American Society of Interventional Pain Physicians (ASIPP) convened a multidisciplinary panel of 51 experts in various fields to review the evidence and formulate recommendations for interventional techniques in managing chronic spinal pain. The panel was instructed to answer questions and develop evidence pertaining to important aspects of spinal interventional techniques. Members of the panel were also requested to develop comprehensive systematic reviews on various related subjects in preparation for the development of spinal interventional techniques guidelines. Other independent systematic reviews were also considered. The panel convened in person on 3 occasions at ASIPP workshops in Memphis, TN, and also had 6 webinars and/or telephone conferences. The majority of participants attended multiple meetings.

The committee provided a broad representation of academic and non-academic clinical practitioners, reflecting a variety of practices and geographic areas, all with interest and expertise in interventional techniques and chronic pain management. The committee formulated the elements of the guideline preparation process, including literature searches, literature synthesis, consensus evaluation, open forum presentations, and formal endorsement by the ASIPP Board of Directors and peer review. However, there were no patients and patient advocates or patient/consumer organizations included in the guideline development process, which may be considered as a deficiency.

The evidence synthesis and analysis resulted in multiple conclusions and recommendations based on evidence with overwhelming majority consent.

Recommendations of the Institute of Medicine (IOM), which essentially incorporate all other guidance for guideline development, were applied in the preparation of ASIPP guidelines. All of the guidelines share a similar philosophy, thus, this guideline development process uses the IOM's 8 proposed standards (see the original guideline for more information; see also Part I in the original guideline document [see the "Availability of Companion Documents" field]).

Grading Recommendations

As recommended by the IOM, for each recommendation, information was provided with an explanation of the reasoning underlying the recommendation, including a clear description of potential benefits and harms; a summary of relevant available evidence; description of the quality, quantity, and consistency of the aggregate available evidence; an explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendations; a rating of the level of confidence; a rating of the strength of recommendation; and a description and explanation of any differences of opinion regarding the recommendation. In grading recommendations, the grading of recommendations from the United States Preventive Services Task Force (USPSTF) was utilized (see the "Rating Scheme for the Strength of the Evidence" field).

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

All the systematic reviews underwent peer review prior to publication. The guidelines were posted for comment from the American Society of Interventional Pain Physicians (ASIPP) membership and others on the website and also widely advertised in the ASIPP newsletter for comments.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is specifically stated for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Implementation of the guidelines may improve the quality of care, patient access, treatment outcomes, appropriateness of indicated and medically necessary care, and efficiency and effectiveness, as well as achieve cost containment by improving the cost-benefit ratio.

Potential Harms

- The simultaneous use of multiple agents that possess anticoagulant properties (e.g., nonsteroidal anti-inflammatory agents [NSAIDs] or aspirin along with selective serotonin re-uptake inhibitors [SSRIs], fish oil, etc.) will increase the risk of morbidity and/or mortality.
- Complications from diagnostic and therapeutic interventions are described in the original guideline document in the sections titled "Complications" for each intervention. Complications, in general, are related to needle placement and drug administration.

Contraindications

Contraindications

In general, contraindications include inability to undergo or tolerate recommended interventional procedures and/or associated drug therapies.

Contraindications may include:

- Extrusion/sequestration type of herniation
- Long-term duration of the symptoms
- Old age
- Calcification of longitudinal ligaments
- Previous surgical discectomy
- Presence of neurological deficit
- Infection
- Coagulopathies
- Severe spinal stenosis resulting in intraspinal obstruction
- Predominantly psychogenic pain

Qualifying Statements

Qualifying Statements

- The authors are solely responsible for the content of this article. No statement on this article should be construed as an official position of

American Society of Interventional Pain Physicians (ASIPP). The guidelines do not represent "standard of care."

- While these guidelines may be applied by any specialty, they are specifically intended for use by interventional pain physicians. These guidelines do not constitute inflexible treatment recommendations. It is expected that a provider will establish a plan of care on a case-by-case basis, taking into account an individual patient's medical condition, personal needs, and preferences, and the physician's experience. Based on an individual patient's needs, treatment different from that outlined here could be warranted. Consequently, these guidelines do not represent a "standard of care."
- The goal of these guidelines is to provide practitioners and payers with information to determine whether the available evidence supports the notion of a "standard" for interventional techniques. "Standard" refers to what is applicable to the majority of patients, with a preference for patient convenience and ease of administration without compromising treatment efficacy or morbidity. It is essential to recognize the difference between "standard" and "standard of care," as utilized as a legal definition.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Manchikanti L, Abdi S, Atluri S, Benyamin RM, Boswell MV, Buenaventura RM, Bryce DA, Burks PA, Caraway DL, Calodney AK, Cash KA, Christo PJ, Cohen SP, Colson J, Conn A, Cordner H, Coubarous S, Datta S, Deer TR, Diwan S, Falco FJ, Fellows B, Geffert S, Grider JS, Gupta S, Hameed H, Hameed M, Hansen H, Helm S 2nd, Janata JW, Justiz R, Kaye AD, Lee M, Manchikanti KN, McManus CD, Onyewu O, Parr AT, Patel VB, Racz GB, Sehgal N, Sharma ML, Simopoulos TT, Singh V, Smith HS, Snook LT, Swicegood JR, Vallejo R, Ward SP, Wargo BW, Zhu J, Hirsch JA. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2003 (revised 2013 Apr)

Guideline Developer(s)

American Society of Interventional Pain Physicians - Medical Specialty Society

Source(s) of Funding

There was no external funding in preparation of this manuscript.

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American Society of Interventional Pain Physicians (ASIPP) Multidisciplinary Panel

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Financial Disclosures/Conflicts of Interest

Management of Conflict of Interest

Conflicts were managed by limiting involvement of the individuals with conflicts of interest and re-evaluating the evidence provided by those with conflicts of interest, even though there was no direct funding received for this project. Consequently, the guideline developers have also undertaken extensive efforts to avoid direct, as well as indirect, internal and external conflicts of interest. Prior to selection of the guideline development group, all the individuals considered for membership declared all interests and activities potentially resulting in conflicts of interest with development group activity, by written disclosure. Disclosures reflected all current and planned commercial services, including services from which a clinician derives a substantial portion of income, noncommercial, intellectual, institutional, and patient/public activities pertinent to the potential scope of the clinical practice guidelines. There were no significant conflicts of interest among the members, thus, there was no necessity for divestment or exclusion. Even then, care was exercised to avoid any conflicts not disclosed by the usual disclosure procedure in decision-making.

Sixteen of the 51 authors provided information that they received funding from industry; however, of these, less than 5% were receiving funding from drug makers, only 2% were receiving from industry, and 2% were receiving funding for research or engaged in speaking from industry. Editorially, appropriate measures were taken to avoid any conflicting opinions from authors receiving funding from the industry.

Conflicts of Interest

Dr. Benjamin is a consultant with Bioness and Nevro; serves on the advisory boards of Vertos Medical and Nuvo Pharma; teaches/lectures for Vertos Medical, Boston Scientific, Neurotherm, and Bioness; and receives research/grants from Alfred Mann Foundation, Teknon Foundation, Spinal Restoration, Inc., Bioness, Boston Scientific, Vertos Medical, Medtronic, Kimberly Clarke, Epimed, BioDelivery Sciences International, Inc., Theravance, Mundipharma Research, Cephalon/Teva, AstraZeneca, and Purdue Pharma, LP.

Dr. Caraway is a consultant for Medtronic, Inc., Bioness, Spinal Modulation, Inc., and Vertos, Inc.

Dr. Calodney is a consultant for Stryker, Inc., Medtronic, Inc., and Nimbus Concepts.

Dr. Cohen served as a funded co-investigator on a Department of Defense Study. He is also a consultant for Halozyne and Kimberly Clark.

Dr. Datta receives research support from Sucampo Pharmaceuticals and an honorarium from Smith and Nephew

Dr. Deer is a consultant and research advisor for Bioness, Flowonix, Jazz, Medtronic, Nevro, St. Jude, Spinal Modulation, and Vertos.

Dr. Falco is a consultant for St. Jude Medical Inc. and Joimax Inc.

Dr. Grider is an educational trainer for Vertos Medical.

Dr. Helm is a clinical investigator with Epimed and receives research support from Cephalon/Teva, Astra Zeneca, and Purdue Pharma, LP. He has attended an advisory group meeting for Activas.

Dr. Justiz is a Consultant for St. Jude, Epimed, Annulex technologies, and currently in a study with Bioness.

Dr. Alan Kaye is a speaker for Depomed, Inc.

Dr. Racz is a Consultant for and has family ownership of Epimed International, is a consultant to Cosman RF company, and has Medtronic patent issues.

Dr. Schultz is a paid consultant for Medtronic.

Dr. Vallejo receives research support from Cephalon/Teva, BioDelivery Sciences International, Inc., Mundipharma Research GmbH & Co., AstraZeneca, Purdue Pharma, LP, and Theravance, and is a consultant for nevro and Kimberly-Clark

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Manchikanti L, Boswell MV, Singh V, Benjamin RM, Fellows B, Abdi S, Buenaventura RM, Corn A, Datta S, Derby R, Falco FJ, Erhart S, Diwan S, Hayek SM, Helm S, Parr AT, Schultz DM, Smith HS, Wolfner LR, Hirsch JA. Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain. *Pain Physician*. 2009 Jul-Aug;12(4):699-802.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the [Pain Physician Journal Web site](#) .

Print copies: Available from the American Society of Interventional Pain Physicians, 2831 Lone Oak Road, Paducah, KY 42003; Phone: (270) 554-9412; Fax: (270) 554-8987; email: asipp@asipp.org.

Availability of Companion Documents

The following is available:

- Manchikanti L, Falco FJE, Singh V, Helm S, Schultz DM, Benjamin RM, Racz GB, Helm II S, Caraway DL, Calodney, AK, Snook, LT, Smith, HS, Gupta, S, Ward, SP, Grider, JS, Hirsch JA. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part I: introduction and general considerations. *Pain Physician* 2013;16:S1-S48. Electronic copies: Available in Portable Document Format (PDF) from the [Pain Physician Journal Web site](#) .

Print copies: Available from the American Society of Interventional Pain Physicians, 2831 Lone Oak Road, Paducah, KY 42003; Phone: (270) 554-9412; Fax: (270) 554-8987; email: asipp@asipp.org.

Patient Resources

None available

NGC Status

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